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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/271,584	03/18/1999	EDUARDO BLUMWALD	4001	4345

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/03/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/271,584

Applicant(s)

BLUMWALD ET AL.

Examiner

Annie R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33, 48, 49 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: detailed action/seq list.

DETAILED ACTION

1. The amendments to claims 1-4, 6-8, 12, 19, 21, 23, 26, 28-29, 31, 53 and 55 requested in Paper No. 19, filed 15 October, 2001, have been entered. Claims 1-33, 48-49, and 53-55 are pending. Claims 15-16, 33 and 48-49 are withdrawn from consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

3. The objection to claims 2-6, 8-14, 17-32 and 55 because they contain nonelected matter is WITHDRAWN in light of amendments to claims 2 and 4 to deleted nonelected sequences.
4. The objection to claims 19, 21, 26 and 31 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim is WITHDRAWN in light of amendments to the claims.
5. The rejection of claims 1-4, 6-11, 17-31 and 55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention is obviated by the following amendments:

replacement of "capable of ..." with "provides" in claims 1-2, 4, 7, 12, 26 and 53,
replacement of "include" and "includes" with "comprise" or "comprises" in claims 28-29,
replacement of "enhances" with "provides" in claim 32,
replacement of references to Tables in claims 3 and 23 with the information in those tables,

correction of the dependency in claim 26, and

correction of spelling claim 2.

Response to Arguments

6. The rejection of claims 32 and 53-54 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is WITHDRAWN in light of arguments from the Applicant. Applicant argued that as the elevated level of polypeptide is compared to the level in a non-transgenic plant in claim 32 and as the increased salt tolerance in claim 53 is compared to a wild-type plant, the terms are not indefinite. Examiner agrees.

Claim Rejections - 35 USC § 112

7. Claims 1-14 and 17-32 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids that encode SEQ ID NO:2, does not reasonably provide enablement for nucleic acids with homology to those nucleic acids or encode fragments of a transporter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 3-6 of the last Office action.

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive.

Applicant urges that the sequences of AtNHX1-4, which are functional vacuolar antiports, provide strong guidance for how to make and/or identify other antiports with activity

similar to that of SEQ ID NO:1, especially as the amino acid identity of the AtNHX2-4 to AtNHX1 is as low as 28%. Applicant urges that this means many variations are possible without impairing antiport activity, and the amino acid alignments in Figs. 2b and 2c indicate the conserved amino acids. Applicant also points out that the specification provides guidance as to the identification of domains within SEQ ID NO:1 and assays for identifying functional vacuolar antiports.

This is not found persuasive because a nucleic acid of SEQ ID NO:1 would hybridize to a nucleic acid that encodes a urea transporter protein (Hediger et al, 19995, US Patent 5441875; see sequence search results sent with the prior Office action). This nucleic acid would be 42.6% similar to a nucleic acid that encodes SEQ ID NO:2. The instant specification fails to provide guidance for which amino acids can be altered, deleted or added to make a Na^+/H^+ transporter versus a urea transporter.

8. Claims 1-14, 17-32 and 53-54 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 6-7 of the last Office action.

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive. Applicant urges that sufficient guidance is provided.

This is not found persuasive because guidance is lacking for alteration of SEQ ID NO:1 to produce a Na^+/H^+ transporter versus other transporters.

9. Claim 1 [amended] is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "not the sequence having GenBank Accession No. AF007271" is not found anywhere in the specification, nor is any mention of GenBank Accession No. AF007271. Thus, this phrase is NEW MATTER.

10. Claims 5 and 12-14 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention, as stated in the prior Office action for claims 1-14, 17-32 and 53-55. Dependent claims are included in the rejection.

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive.

Applicant urges that amendments to the claims obviate most of the indefiniteness rejections. Applicant also urges that the term "elevated" in claim 32 is not indefinite because the elevated polypeptide is relative to a non-transgenic plant and the application provides assays for determining the amount of polypeptide. Similarly, Applicant argues that "increased" in claims 12 and 53 is not indefinite.

This is not found persuasive because claim 5 was not amended. In claim 12, the increase in salt tolerance is not compared to the level of salt tolerance in a non-transformed plant.

Claim Rejections - 35 USC § 102

11. Claims 1-14, 17, 19-20 and 26 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brant et al (1997, GenBank Accession No. T51330).

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive. Applicant urges that the present claims are drawn to a plant transporter while Brant et al teaches a human Na^+/H^+ transporter.

This is not found persuasive because the claims are drawn to a nucleic acid encoding a transporter capable of increasing salt tolerance in a cell, the definition of TNHx found on pg 20, lines 23-26 of the specification, or to a polypeptide that has Na^+/H^+ transporter activity, or a fragment of a polypeptide with Na^+/H^+ transporter activity, where the nucleic acid hybridizes to all or part of SEQ ID NO:1 or is degenerate to such a nucleic acid or has at least 30% identity to a nucleic acid that encodes SEQ ID NO:2. The nucleic acid taught by Brant et al fits those criteria because it encodes a Na^+/H^+ transporter, some portion of the nucleic acid would hybridize to SEQ ID NO:1, would comprise a part of SEQ ID NO:1, and it has 61.8% identity to a nucleic acid that encodes SEQ ID NO:2 (see sequence search results sent with the prior Office action). The claims are not solely drawn to a plant transporter and the nucleic acid of Brant et al would encode a transporter that would extrude monovalent cations from a cell, including a plant cell.

12. Claims 1-14, 17, 19-20 and 26 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sumitomo Sieyaku KK (1993, GenBank Accession No. Q51524).

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive. Applicant urges that Sieyaku teaches a rabbit Na^+/H^+ transporter while the present claims are directed to a plant transporter.

This is not found persuasive because the claims are drawn to a nucleic acid encoding a transporter capable of increasing salt tolerance in a cell, or to a polypeptide that has Na^+/H^+ transporter activity, or a fragment of a polypeptide with Na^+/H^+ transporter activity, where the nucleic acid hybridizes to all or part of SEQ ID NO:1 or is degenerate to such a nucleic acid or has at least 30% identity to a nucleic acid that encodes SEQ ID NO:2. The nucleic acid taught by Sieyaku fits those criteria because it encodes a Na^+/H^+ transporter, some portion of the nucleic acid would hybridize to SEQ ID NO:1, would comprise a part of SEQ ID NO:1, and it has 56.5% identity to a nucleic acid that encodes SEQ ID NO:2 (see sequence search results sent with the prior Office action). The claims are not solely drawn to a plant transporter and the nucleic acid of Sieyaku would encode a transporter that would extrude monovalent cations from a cell, including a plant cell.

13. Claims 2-14, 17, 19-20 and 26 remain rejected under 35 U.S.C. 102(a) as being anticipated by Dante et al (1997, GenBank Accession No. AF007271), as stated in the prior action for claims 1-14, 17, 19-20 and 26.

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive.

Applicant urges that there is no peptide in *Arabidopsis* that has the sequence of Dante et al. Applicant argues that Dante et al discloses a predicted amino acid sequence generated using a computer program and the sequence is incorrect because the program erred in predicting introns

and exons. Applicant also argues that Dante et al never possessed an isolated and cloned sequence nor teaches its successful isolation. Applicant also argues that the nucleic acid of Dante et al is merely described as being similar to a Na^+/H^+ transporter and no proof of function was provided; as such, one of skill in the art would not have an expectation of producing a salt tolerant plant with the sequence.

This is not found persuasive because Dante et al teach a genomic clone that encodes the protein of SEQ ID NO:2 (see sequence search results sent with the prior action and the enclosed results). As the nucleic acid would inherently encode SEQ ID NO:2, regardless of the vagaries of any computer program used to analyze it, and as it is identical to SEQ ID NO:1, except for the introns, it is not necessary for Dante et al to have accurately described the protein encoded by AF007271 nor to have proved function of the encoded protein. Additionally, Dante et al did isolate this nucleic acid, in the form of BAC clone TM021B04.

14. Claims 1-3, 5-14, 17-20, 26 and 31 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hahnenberger et al (1996, Proc. Natl. Acad. Sci., USA 93:5031-5036), as stated in the prior Office action for claims 1-14, 17-20, 26 and 31.

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive.

Applicant urges that Hahnenberger et al teach a yeast Na^+/H^+ transporter while the present claims are directed to a plant transporter. Applicant also argues that the transporter of Hahnenberger et al has no sequence similarity to the transporter of the instant invention.

This is not found persuasive because as discussed above the claims are not drawn to a plant transporter. The nucleic acid taught by Hahnenberger et al encodes a Na^+/H^+ transporter,

some portion of the nucleic acid would hybridize to SEQ ID NO:1, and it would comprise a part of SEQ ID NO:1.

15. Claims 1-3, 5-14, 17-24, 26-32 and 53-54 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Young et al (WO 91/06651), as stated in the prior Office action for claims 1-14, 17-24, 26-32 and 53-54.

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive.

Applicant urges that Young et al teach a yeast Na^+/H^+ transporter while the present claims are directed to a plant transporter. Applicant also argues that the transporter of Young et al has no sequence similarity to the transporter of the instant invention.

This is not found persuasive because as discussed above the claims are not drawn to a plant transporter. The nucleic acid taught by Young et al encodes a Na^+/H^+ transporter, some portion of the nucleic acid would hybridize to SEQ ID NO:1, and it would comprise a part of SEQ ID NO:1. Young et al also teach that that plants transformed with the nucleic acid would be resistant to high sodium concentration (pg 9, paragraph 1). The *sod2* gene encodes a TNHx transporter, which the instant specification defines as a Na^+/H^+ transporter that is capable of increasing salt tolerance in a cell (pg 20, lines 23-24).

Claim Rejections - 35 USC § 103

16. Claims 1-3, 5-14, 17-32 and 53-54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (WO 91/06651) in view of Gordon-Kamm et al (1990, Plant Cell 2:603-618), as stated in the prior Office action for claims 1-14, 17-32 and 53-54.

Applicant's arguments filed 15 October, 2001 have been fully considered but they are not persuasive.

Applicant urges that neither Young et al or Gordon-Kamm et al teach a nucleic acid encoding a plant Na^+/H^+ transporter and that many skilled in the art did not believe that salt tolerance could be conferred on a plant by transformed with a single gene.

This is not found persuasive because as discussed in the prior Office action, Young et al teach tobacco and *Arabidopsis* plants transformed with a gene encoding the Na^+/H^+ transporter *sod2* (pg 28, paragraph 3, to pg 35). Young et al also demonstrate that transformed plants tolerated the salt LiCl better than did control plants (paragraph spanning pg 34-35).

17. Claim 55 is free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid of SEQ ID NO:1.

Claim Objections

18. Claim 55 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

19. No claim is allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1638

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm. Questions can also be addressed to the patent analyst, Dianeice Jacobs, at (703) 305-3388.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.
November 28, 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

